

## **REMARKS**

Withdrawn claims 31-41 have been canceled without prejudice to resubmission. Claim 15 has been amended. Upon entry of this amendment, claims 15-30 will remain pending in the present application.

### **I. Claim Amendments**

Claim 15 has been amended to require that the distal ends of the arms are adapted to support at least a portion of said hollow structures and hold said joining elements while positioning at least one said hollow structure relative to said joining elements for making an anastomosis between the hollow structures by moving said arms from said first position to said second position. Basis for this amendment is found, for example, at page 13, lines 13-28, and page 8, lines 29-37 of the application as originally filed.

### **II. The Rejection Under 35 U.S.C. 102(e)**

Claims 15-30 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent no. 5,720,755 (Dakov). This rejection, at least insofar as it applies to claims 15-30, as amended, is traversed and reconsideration is requested for the reasons which follow.

The applicator of the present claims 15-30 is adapted for anastomosis via two distinct actions:

1. Tissue presentation which is done by expansion of the applicator, and
2. Tissue bonding which is done by permanently deforming the joining elements.

This sequence has proven, in practice, to be extremely important since proper tissue presentation by device expansion, to stretch the vessel walls around the applicator, positions the vessel walls for deployment of the staples to make the connection. This method minimizes errors in tissue capture by the staples (e.g. missing a part of the vessel wall – See page 13, lines 25-28 of the specification) thereby greatly enhancing the reliability of the anastomosis.

The important point is that the device of figures 12A-12F of Dakov does not provide the ability to stretch the tissue of the vessel around the applicator before penetrating the tissue with the staples. This can be seen from the fact that the staples 206 of Dakov are moved outwardly to penetrate the tissue by the expansion of arms 214b. See e.g. col. 12, lines 21-30 of Dakov. As a result, the tissue must already be properly positioned for stapling prior to expansion of the device of Dakov since stapling occurs during expansion of the device. Dakov cannot first stretch the tissue around the applicator as in

the present device since the movable arms of Dakov are surrounded by a static tube 204, preventing the arms from carrying out such a function. This is difficult in practice and increases the chance that staples will miss part of the vessel wall, thereby decreasing the reliability of the anastomosis.

Claim 15, as amended, distinguishes over the device of figures 12A-12E of Dakov since claim 15 requires require that the distal ends of the arms are adapted to support at least a portion of said hollow structures and hold said joining elements while positioning at least one said hollow structure relative to said joining elements for making an anastomosis between the hollow structures by moving said arms from said first position to said second position. As discussed above, the device of Dakov does not support at least a portion of the hollow structure while positioning at least one hollow structure relative to said joining elements since Dakov is incapable of carrying out this function due to the presence of static tube 204 surrounding the device.

Accordingly, for at least this reason, claim 15 is considered to be novel over Dakov. Claims 16-30 all depend from claim 15 and thus are considered to be novel over Dakov for at least the same reason as claim 15, as amended. Favorable consideration and withdrawal of the novelty objection over Dakov is requested.

In addition, claims 15-30 are considered to be unobvious over Dakov since a skilled person would have no reason to remove static tube 204 from the device of figures 12A-12F of Dakov, as would be required to meet the limitations of the present claims, as discussed above. The reason for this is that static tube 204 includes predefined passages for guiding the movement of arms 214 and staples 206 in the device of Dakov and thus without such predefined passages in the static tube 204, the device of Dakov would not function.

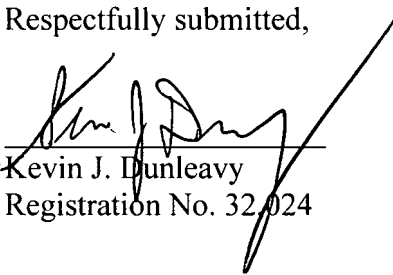
Also, the device of figures 12A-12F of Dakov is not suitable for a two-step anastomosis, as is the presently claimed applicator. More particularly, the device of Dakov, due to its design, must penetrate the vessel wall with the staples while expanding the arms since expansion of the arms is the mechanism which causes the staples to penetrate the tissue. In the present device, the staples do not penetrate the tissue as a result of the expansion of the arms, but rather as a result of a separate step, movement of the detainer. This allows a two-step process of first positioning the tissue and second penetrating the tissue with staples, in order to provide a more reliable connection due to less staples missing the vessel walls.

### III. The Obviousness-Type Double-Patenting Rejection

A Terminal Disclaimer has been submitted herewith in order to obviate the obviousness-type double patenting rejection. Withdrawal of the rejection in view of the submission of the Terminal Disclaimer is requested.

Favorable consideration and issuance of a Notice of Allowance is requested.

Respectfully submitted,



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Enclosures: Terminal Disclaimer and Check in the amount of \$290 for fee for two month extension (\$225) and Terminal Disclaimer Fee (\$65).